

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I**, claim(s) 1-3, 5-10, and 11-15, drawn to a chemical compound and a pharmaceutical composition of formula (I) wherein R<sup>3</sup> and R<sup>4</sup> do not form a ring.

**Group II**, claim(s) 1, 2, 4, 5, 7, 9, and 13-15, drawn to a chemical compound and a pharmaceutical composition of formula (I) wherein R<sup>3</sup> and R<sup>4</sup> do form a ring.

**Group III**, claim(s) 16, drawn to a method of treatment of asthma; chronic bronchitis; chronic obstructive pulmonary disease; adult respiratory distress syndrome; infant respiratory distress syndrome; cough; chronic obstructive pulmonary disease in animals; or adult respiratory distress syndrome using a chemical a chemical compound of Group I.

**Group IV**, claim(s) 16, drawn to a method of treatment of asthma; chronic bronchitis; chronic obstructive pulmonary disease; adult respiratory distress syndrome; infant respiratory distress syndrome; cough; chronic obstructive pulmonary disease in animals; or adult respiratory distress syndrome using a chemical a chemical compound of Group II.

**Group V**, claim(s) 16, drawn to a method of prevention of asthma; chronic bronchitis; chronic obstructive pulmonary disease; adult respiratory distress

syndrome; infant respiratory distress syndrome; cough; chronic obstructive pulmonary disease in animals; or adult respiratory distress syndrome using a chemical a chemical compound of Group I.

**Group VI**, claim(s) 16, drawn to a method of prevention of asthma; chronic bronchitis; chronic obstructive pulmonary disease; adult respiratory distress syndrome; infant respiratory distress syndrome; cough; chronic obstructive pulmonary disease in animals; or adult respiratory distress syndrome using a chemical a chemical compound of Group II.

**Group VII**, claim(s) 16, drawn to a method of treatment of ulcerative colitis; Crohn's disease; or hypersecretion of gastric acid using a chemical compound of Group I.

**Group VIII**, claim(s) 16, drawn to a method of treatment ulcerative colitis; Crohn's disease; or hypersecretion of gastric acid using a chemical compound of Group II.

**Group IX**, claim(s) 16, drawn to a method of prevention of ulcerative colitis; Crohn's disease; or hypersecretion of gastric acid using a chemical compound of Group I.

**Group X**, claim(s) 16, drawn to a method of prevention of ulcerative colitis; Crohn's disease; or hypersecretion of gastric acid using a chemical compound of Group II.

**Group XI**, claim(s) 16, drawn to a method of treatment of bacterial, fungal or viral induced sepsis or septic shock; endotoxic shock; laminitis or colic in horses

using a chemical compound of Group I.

**Group XII**, claim(s) 16, drawn to a method of treatment of bacterial, fungal or viral induced sepsis or septic shock; endotoxic shock; laminitis or colic in horses using a chemical compound of Group II.

**Group XIII**, claim(s) 16, drawn to a method of prevention of bacterial, fungal or viral induced sepsis or septic shock; endotoxic shock; laminitis or colic in horses using a chemical compound of Group I.

**Group XIV**, claim(s) 16, drawn to a method of prevention of bacterial, fungal or viral induced sepsis or septic shock; endotoxic shock; laminitis or colic in horses using a chemical compound of Group II.

**Group XV**, claim(s) 16, drawn to a method of treatment of spinal cord trauma; head injury; neurogenic inflammation; pain; or reperfusion injury of the brain using a chemical compound of Group I.

**Group XVI**, claim(s) 16, drawn to a method of treatment of spinal cord trauma; head injury; neurogenic inflammation; pain; or reperfusion injury of the brain using a chemical compound of Group II.

**Group XVII**, claim(s) 16, drawn to a method of prevention of spinal cord trauma; head injury; neurogenic inflammation; pain; or reperfusion injury of the brain using a chemical compound of Group I.

**Group XVIII**, claim(s) 16, drawn to a method of prevention of spinal cord trauma; head injury; neurogenic inflammation; pain; or reperfusion injury of the brain using a chemical compound of Group II.

**Group XIX**, claim(s) 16, drawn to a method of treatment of psoriatic arthritis; rheumatoid arthritis; ankylosing spondylitis; osteoarthritis; inflammation; or cytokine-mediated chronic tissue degeneration using a chemical compound of Group I.

**Group XX**, claim(s) 16, drawn to a method of treatment of psoriatic arthritis; rheumatoid arthritis; ankylosing spondylitis; osteoarthritis; inflammation; or cytokine-mediated chronic tissue degeneration using a chemical compound of Group II.

**Group XXI**, claim(s) 16, drawn to a method of prevention of psoriatic arthritis; rheumatoid arthritis; ankylosing spondylitis; osteoarthritis; inflammation; or cytokine-mediated chronic tissue degeneration using a chemical compound of Group I.

**Group XXII**, claim(s) 16, drawn to a method of prevention of psoriatic arthritis; rheumatoid arthritis; ankylosing spondylitis; osteoarthritis; inflammation; or cytokine-mediated chronic tissue degeneration using a chemical compound of Group II.

**Group XXIII**, claim(s) 17, drawn to a method of treatment of allergic rhinitis, allergic conjunctivitis, or eosinophilic granuloma using a chemical compound of Group I.

**Group XXIV**, claim(s) 17, drawn to a method of treatment of allergic rhinitis, allergic conjunctivitis, or eosinophilic granuloma using a chemical compound of Group II.

**Group XXV**, claim(s) 17, drawn to a method of prevention of allergic rhinitis, allergic conjunctivitis, or eosinophilic granuloma using a chemical compound of Group I.

**Group XXVI**, claim(s) 17, drawn to a method of prevention of allergic rhinitis, allergic conjunctivitis, or eosinophilic granuloma using a chemical compound of Group II.

**Group XXVII**, claim(s) 17, drawn to a method of treatment of osteoporosis using a chemical compound of Group I.

**Group XXVIII**, claim(s) 17, drawn to a method of treatment of osteoporosis using a chemical compound of Group II.

**Group XXIX**, claim(s) 17, drawn to a method of prevention of osteoporosis using a chemical compound of Group I.

**Group XXX**, claim(s) 17, drawn to a method of prevention of osteoporosis, using a chemical compound of Group II.

**Group XXXI**, claim(s) 17, drawn to a method of treatment of arterial restenosis, atherosclerosis, or reperfusion injury of the myocardium chronic glomerulonephritis using a chemical compound of Group I.

**Group XXXII**, claim(s) 17, drawn to a method of treatment of arterial restenosis, atherosclerosis, or reperfusion injury of the myocardium chronic glomerulonephritis using a chemical compound of Group II.

**Group XXXIII**, claim(s) 17, drawn to a method of prevention of arterial restenosis, atherosclerosis, or reperfusion injury of the myocardium chronic

glomerulonephritis using a chemical compound of Group I.

**Group XXXIV**, claim(s) 17, drawn to a method of prevention of arterial restenosis, atherosclerosis, or reperfusion injury of the myocardium chronic glomerulonephritis using a chemical compound of Group II.

**Group XXXV**, claim(s) 17, drawn to a method of treatment of vernal conjunctivitis, cachexia, transplant rejection, or graft versus host disease using a chemical compound of Group I.

**Group XXXVI**, claim(s) 17, drawn to a method of treatment of vernal conjunctivitis, cachexia, transplant rejection, or graft versus host disease using a chemical compound of Group II.

**Group XXXVII**, claim(s) 17, drawn to a method of prevention of vernal conjunctivitis, cachexia, transplant rejection, or graft versus host disease using a chemical compound of Group I.

**Group XXXVIII**, claim(s) 17, drawn to a method of prevention of vernal conjunctivitis, cachexia, transplant rejection, or graft versus host disease using a chemical compound of Group II.

**Group XXXIX**, claim(s) 18, drawn to a method of treatment of depression, memory impairment, or monopolar depression using a chemical compound of Group I.

**Group XL**, claim(s) 18, drawn to a method of treatment of depression, memory impairment, or monopolar depression using a chemical compound of Group II.

**Group XLI**, claim(s) 18, drawn to a method of prevention of depression, memory impairment, or monopolar depression using a chemical compound of Group I.

**Group XLII**, claim(s) 18, drawn to a method of prevention of depression, memory impairment, or monopolar depression using a chemical compound of Group II.

**Group XLIII**, claim(s) 18, drawn to a method of treatment of Parkinson disease, Alzheimer's disease, or acute and chronic multiple sclerosis using a chemical compound of Group I.

**Group XLIV**, claim(s) 18, drawn to a method of treatment of Parkinson disease, Alzheimer's disease, or acute and chronic multiple sclerosis using a chemical compound of Group II.

**Group XLV**, claim(s) 18, drawn to a method of prevention of Parkinson disease, Alzheimer's disease, or acute and chronic multiple sclerosis using a chemical compound of Group I.

**Group XLVI**, claim(s) 18, drawn to a method of prevention of Parkinson disease, Alzheimer's disease, or acute and chronic multiple sclerosis using a chemical compound of Group II.

**Group XLVII**, claim(s) 18, drawn to a method of treatment of psoriasis, benign or malignant proliferative skin diseases, atopic dermatitis, or urticaria using a chemical compound of Group I.

**Group XLVIII**, claim(s) 18, drawn to a method of treatment of psoriasis, benign

or malignant proliferative skin diseases, atopic dermatitis, or urticaria using a chemical compound of Group II.

**Group XLIX**, claim(s) 18, drawn to a method of prevention of psoriasis, benign or malignant proliferative skin diseases, atopic dermatitis, or urticaria using a chemical compound of Group I.

**Group L**, claim(s) 18, drawn to a method of prevention of psoriasis, benign or malignant proliferative skin diseases, atopic dermatitis, or urticaria using a chemical compound of Group II.

**Group LI**, claim(s) 18, drawn to a method of treatment of cancer, tumor growth or cancerous invasion of normal tissues using a chemical compound of Group I.

**Group LII**, claim(s) 18, drawn to a method of treatment of cancer, tumor growth or cancerous invasion of normal tissues using a chemical compound of Group II.

**Group LIII**, claim(s) 18, drawn to a method of prevention of cancer, tumor growth or cancerous invasion of normal tissues using a chemical compound of Group I.

**Group LIV**, claim(s) 18, drawn to a method of prevention of cancer, tumor growth or cancerous invasion of normal tissues using a chemical compound of Group II.

2. The inventions listed as Groups I-LIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: a common structure is not present in which the utility is attributed.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows: the radicals defined by R<sup>1</sup>, R<sup>2</sup>, X, R<sup>3</sup>, and R<sup>4</sup>.

4. Applicant is required under 35 U.S.C. 121 to elect a ***single disclosed species*** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. If Group LI, LII, LIII, or LIV is the elected group, a single disclosed disease state should be further elected.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

- (b) the prior art applicable to one invention would not likely be applicable to another invention;
- (c) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

7. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

8. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

11. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

12. Due to the complexity of the restriction requirement, a written requirement is made.

13. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682.

16. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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